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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/032,191 | 12/21/2001 | Philippe Collas | 50195/003002 | 4902 |
| 21559 | 7590 | 05/18/2004 | EXAMINER | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | WOITACH, JOSEPH T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

374

Office Action Summary**Application No.**

10/032,191

Applicant(s)

COLLAS ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 16-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application filed January 9, 2002, claims benefit to provisional application 60/258,151, filed December 22, 2000.

Claims 1-42 are pending and currently under examination.

Election/Restriction

Applicant's election without traverse of Group I, claims 1-15, drawn to a method of cloning a non-human mammal comprising incubating a permeabilized cell in a reprogramming media to form a reprogrammed cell is acknowledged. Claims 16-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. It appears only to set forth a description of what occurs after practicing the steps of claim 1. There are no specific steps that

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more narrowly define the method or set forth how one would practice the method set forth in claim 1 that would result in any other affect than that set forth in claim 15. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

Claim 1 is unclear in the metes and bounds of a “permeabilized cell”. It is noted that the specification indicates that by “ “permeabilization” is meant the formation of pores in the plasma membrane or the partial or complete removal of the plasma membrane” (page 14, lines 29-30), however this is unclear how this applies in the context of providing a cell for use in the claimed methods. It appears from the definition provided in the specification that the claims include providing an isolated nucleus, however this would be inconsistent with the term “cell” as it is recognized in the art. Further, in light of the definition it is unclear if the claims even encompass providing chromosomes absent any membrane. In addition, it is unclear how this state is related to providing the removal or addition of factors from the nucleus. It is unclear if permeabilization simply allows for the transfer of products in and out, or if the delivery can be affected by a secondary means such as transfection with a liposome composition. Finally, it is

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unclear what is being remove and/or added such that in any case the resulting “reprogrammed cell” can result in a fetus. It is unclear what or how agents can be both added or removed and still result in a cell that results in a fetus, in particular, because simply providing the fusion of a somatic cell to an oocyte under art recognized conditions can result in a viable fetus and offspring.

Claim 5 is unclear in the recitation of “to reseal” because the claims appear to encompass the complete removal of the membrane. It is unclear if by reseal if the membrane must be added back in these circumstances.

Claim 15 is unclear in how it further limits the method set forth in claim 1. It appears only to set forth a description of what occurs after practicing the steps of claim 1. There are no specific steps that more narrowly define the method or set forth how one would practice the method set forth in claim 1 that would result in any other affect than that set forth in claim 15.

Claim 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are the specific conditions under which the permeabilized cell is provided for use in step (a) and the specific agents that result in reprogramming of the cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
(f) he did not himself invent the subject matter sought to be patented.

Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Robl *et al.* (2004/0068760) and Collas *et al.* (2002/0142397 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In each case, the specification and the claimed invention encompasses the inventions instantly claimed. For example, compare claim 43 of 2004/0068760 or 16 of 2002/0142397 with claim 1.

Claims 1-15 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As indicated above, the instantly claimed invention is set forth in the specification and is encompassed in practicing the methods set forth in Robl *et al.* (2004/0068760) and Collas *et al.* (2002/0142397 A1). However, the inventive entity of each of the applications is different.

Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Chapman (US Patent Pub. No. 2002/0001842 A1).

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Chapman teaches a method wherein a cell is de-differentiated by the introduction of cytoplasm from a more primitive cell (see summary in abstract). Chapman teaches that the reprogrammed cell can be made and used in nuclear transfer methodology to result in cloned animals (columns 1-3).

Claims 1, 3, 7 and 9-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Machatay *et al.* (US Patent 6,211,429).

The present claims broadly encompass providing an isolated nucleus to an oocyte, and using said resulting cell to produce a cloned fetus. As such, the present methods encompass nuclear transfer methodology. Machatay *et al.* teach the activation of an oocyte for application in nuclear transfer methodology. It is taught that the nucleus of a cell can be isolated by a variety of methods by methods known and used in the art (see for examples bridging columns 9-10).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Applications Robl *et al.* (2004/0068760) and Collas *et al.* (2002/0142397 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the claimed inventions encompass the same method steps to reprogram a donor cell and using said reprogrammed cell in methods to develop a fetus (to derive ES cells) or viable offspring.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

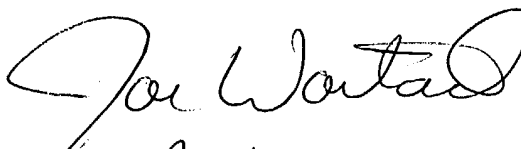
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571)272-0532.

Joseph T. Woitach


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